Effect of heavy slow resistance exercise in adults with frozen shoulder: a randomized controlled trial(HSRFSRCT)

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Introduction and Background

Frozen shoulder is characterized by painful limitation of active and passive range of motion (ROM) of the shoulder. People describe pain, which can be severe, an inability to sleep on the affected side, loss of shoulder function in activities of daily living and limited movements that can lead to chronic stiffness.

Physiotherapy is one of the main treatments which aims to reduce pain, and regain mobility, muscle strength and optimal daily function. There is global loss of both passive and active ROM of the glenohumeral joint, with external rotation usually being the most restricted physiologic movement. Although frozen shoulder is frequently described as a self-limiting condition with gradual spontaneous recovery ,the condition typically has mean duration of 30 months.

Individuals with primary frozen shoulder are commonly between 40 and 65 years old, and the incidence appears 4 times higher in females than males. The condition generally presents unilaterally with the non-dominant shoulder more commonly affected.

Frozen shoulder is "a condition difficult to define, difficult to treat, and difficult to explain from the point of view of pathology(Codman 1935) . The term adhesive capsulitis was introduced by Nevaiser to describe the inflamed and fibrotic condition of the capsule sticking to the humerus. But this term does not appear to appropriately describe the condition and arguably term should be abandoned as explained by Lundberg (1979).

The etiological explanation of frozen shoulder was directed toward two theories, contraction of the capsule and adhesions of the capsule which were running parallel. Some histological findings show that there is contraction of the capsule. In 1969, Lundberg came with the term frozen shoulder syndrome. In 2014, Jeremy Lewis came out with the term frozen shoulder contraction syndrome. It is likely that limitations in range of motion and the pain associated with frozen shoulder are not only related to capsular and ligamentous tightness, but also fascial restrictions, muscular tightness, and trigger points within the muscles. Physical therapists can address impairments and limitations associated each of these contributors to the pathology of frozen shoulder with a variety of treatment methods.

A meta-analysis suggested that glucocorticoid injections combined with exercise and manual therapy may provide improvement in range of motion .

Intensive mobilization may be more effective than other methods but mostly for late stages of the disease. Rehabilitation programs consisting of exercise, and modalities have been shown to improve shoulder ROM in all planes except external and internal rotation .

One study also showed that supervised neglect physical therapy worked better than intensive physical therapy .

A 2013 RCT showed short term improvement in function and range of motion in the painful phase using intra-articular corticosteroid . A 2016 study showed adding mobilsation to stretching patients had a long-term improvement in function and passive range of motion at one year follow up .

In a review of 31 studies in 2012, Maund et al concluded that there is limited clinical evidence on the effectiveness of treatments for primary frozen shoulder .

The UK FROST trial compared early structured physiotherapy, manipulation under anesthesia and arthroscopic capsular release. All three treatment options led to substantial improvements in pain and function and none of the treatments were superior to each other in the long term follow up

A recent study by Hollmann et al (2018) has demonstrated that muscle guarding may be a significant contributing factor to shoulder movement deficits in some patients suffering from frozen shoulder In a sample of five patients with an indication for capsulotomy, they found that under general anesthesia, the movement of the affected shoulder was less restricted. All patients showed a significant increase in their passive range of motion (ROM), especially in abduction while under general anesthesia conditions, compared to their ROM while awake.

This finding supports the hypotheses that the fear of pain or the fact that little used tissue can be more easily damaged can produce a fear-based brain reaction and generate a muscle defense response that could lead to Frozen Shoulder. So, this may be the major contributing factor to movement restriction in some of these patients although more research is needed to determine the number of patients suffering from this type of Frozen shoulder.

One study by Donatelli et al shows promising results with low load prolonged stretch in frozen shoulder but there is no evidence for high load training.

An RCT by Annales et al showed that adding heavy load eccentric training resulted in a higher gain of isometric strength at 90 degrees of scapular abduction in subacromial impingement. Another study shows that a 12-week-isolated eccentric training program of the rotator cuff is beneficial for shoulder function and pain after 26 weeks in patients with rotator cuff tendinopathy . A systemic literature review shows that eccentric exercise may provide a small but likely not clinically important reduction in pain compared with other types of exercise in patients with subacromial impingement syndrome. But the load used on these studies were low. A systemic review by Kieren O sullivan shows eccentric training can improve strength and reduce the risk of injury in lower limb and facilitate increased muscle flexibility via sarcomerogenesis.

The forces applied during inferior glenohumeral mobilizations may vary between 3 to 14 kg (Witt 2016). A Japanese researcher Eiji Itoi (1993) found that 683 kg/cm2 of force is required to stretch the posterior glenohumeral joint capsule. The heaviest dead lift is 472 kg (2018 world record) is still not enough to stretch the capsule. Most of the frozen shoulder contraction syndrome may be due to muscle inhibition, as the capsule cannot be stretched. So, exercise, stretching, mobilization procedures are suggested to decrease the muscle guarding.

This study focuses on the hypothesis that a heavy slow resistance exercises may have a role on muscle guarding in these cases. As there is evidence that frozen shoulder could be further complicated with muscle guarding which could further complicate the capsular adhesion, and hence a heavy slow resistance exercise is an effective therapeutic intervention which could control the muscle guarding status around the shoulder.

Objective
The objective of this study is to compare the effect of heavy slow resistance exercises with conventional physical therapy alone for the management of frozen shoulder using double-blind randomized controlled trial design.

Methods
The study will employ a double-blind randomized controlled study design. Ethical approval has been obtained from Kuwait Ministry of Health, Ethics committee. Written informed consent will be completed. Seventy patients both Kuwaitis and non-Kuwaitis with frozen shoulder attending the outpatient department of the Al Farwaniya hospital and PM& R hospital will be randomly assigned to the heavy slow resistance exercises group and the control group.

Sample size
Shoulder external rotation range of motion is considered as the primary outcome measure for the proposed study. A study by Celik (2010) [24] was used to inform the sample size calculation, where the shoulder external rotation was measured at baseline and at 12-week post intervention for the glenohumeral range of motion exercise group. Using the means and standard deviations of 22 (12.5) degrees and 33 (14.9) degrees for external rotation range of motion changes resulted in an effect size of -0.799. With a two tailed hypothesis, the minimum required sample size is 30 patients per group at (α) 0.05 and a power (1- ß) of 85%. 35 participants per group will be recruited to account for attrition.

Randomization/Blinding
Participants will be randomly assigned following simple envelope randomization procedures to one of the two treatment groups. Patients will be blinded from the treatment group, and the examinations will be performed by a blinded examiner.

Intervention
Both groups will receive conventional therapy sessions which include active ROM exercise, strengthening and stretching exercises, end-range mobilization and hot packs (if indicated). Exercises will be given within the pain threshold limit twice a week for 12 weeks. In addition, the experimental group will receive heavy slow resistance exercise program using a a theratube. The exact management approach will be standardized between the two groups in terms of intensity and frequency and the experimental group will only receive additional heavy slow resistance exercise.

Subjects will be assessed at baseline and at 3, 6, and 12 months. Shoulder external rotation and abduction ROM will be measured and compared within and between groups and will be analyzed using a One-way ANOVA.

Inclusion Criteria
Inclusion criteria are males and females, Kuwaiti and non-Kuwaiti between 40 and 65 years with unilateral painful, restricted active and passive range of motion of the shoulder, with loss of passive external rotation of at least 50% compared to opposite side at 0 degrees of abduction and with normal X ray findings]. Patients will be included if symptoms present for at least 3 months (Cyriax, 1993; Griggs et al., 2000).

Exclusion Criteria
Severe degeneration, or trauma involving the shoulder (ie, rheumatoid arthritis, osteoarthritis, history of injury to the labrum or articular cartilage or malignancies in the shoulder region, etc.).
Neurologic diseases such as stroke or peripheral nerve neuropathy.
Pain or disorders of the cervical spine, elbow, wrist, or hand.
Pregnancy, cardiac, respiratory, kidney, or circulatory problems pregnancy.
History of fractures, treatment, or surgery to the lumbar spine, thoracic spine, cervical spine, and upper limbs
Injection with corticosteroids in the affected shoulder in the preceding 4 weeks.
Subjects with diabetes mellitus will be accepted.
Inflammatory joint disease affecting the shoulder.
Bilateral frozen shoulder due to possible underlying systemic cause.

Outcome Measures
The primary outcome measure is shoulder range of motion (active and passive shoulder abduction, and active and passive shoulder external rotation) measured by smartphone inclinometer (clinometer plaincode). The secondary outcome measures will be functional outcome measures [measured by the quick Disabilities of the Arm, Shoulder and Hand (Quick DASH) questionnaire and pain [measured using a visual analogue scale (VAS)] and SF-12 and Oxford Shoulder Score (OSS).

Data analysis
SPSS will be used for statistical analysis. All outcome measures will be analyzed using one-way ANOVA.